UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

REBECCA DANDY, Plaintiff, v. ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of ETHICON, INC., GYNECARE, a Division of ETHICON, INC., ETHICON, INC., and JOHNSON & JOHNSON, Defendants.	:	Civil Action No. 20-431 (MAS) (DEA) Hon. Michael A. Shipp, U.S.D.J. Hon. Douglas E. Arpert, U.S.M.J.

DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW AT THE CLOSE OF ALL EVIDENCE

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Defendants Ethicon, Inc., on its own behalf and on behalf of its division, Ethicon Women's Health and Urology (also incorrectly named as "Gynecare"), and Johnson & Johnson (collectively, "Defendants" or "Ethicon") move for judgment as a matter of law under Federal Rule of Civil Procedure 50(a). A party is entitled to judgment as a matter of law where a "reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1). The Court "must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Goodman v. Pa. Tpk. Comm'n*, 293 F.3d 655, 664 (3d Cir. 2002) (quoting *Reeves v. Sanderson Plumbing Prods.*, 530 U.S. 133, 150 (2000)). "Key to surviving a Rule 50 motion is a legally sufficient evidentiary basis for the verdict." *Id*.

Plaintiff's negligent design claim fails for lack of proof of a safer alternative design under Michigan law, and because any claim based on a change in mesh material is preempted. Finally, Plaintiff cannot establish that she has suffered the loss of a vital bodily function to satisfy an exception Michigan's noneconomic damages cap.[1]

[1] On May 1, 2023, the Court granted judgment as a matter of law in Defendants' favor on punitive damages and on a separate exception to *all* caps under the Michigan noneconomic caps statute.

ARGUMENT

I. Plaintiff has not established a safer alternative design for the TVT-O under Michigan law.

On a claim for design defect under Michigan law, the plaintiff must establish that "according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have ***prevented the harm without significantly impairing the usefulness or desirability of the product to users*** and ***without creating equal or greater risk of harm to others***." Mich. Comp. Law 600.2946(2) (emphasis added). An alternative design is "practical and feasible" under the statute "only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was ***developed***, ***available***, and ***capable of use*** in the production of the product and was ***economically feasible*** for use by the manufacturer." *Id.* (emphasis added). The statute provides that economic feasibility cannot be established "if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability." *Id.*

Plaintiff bears the burden of offering sufficient affirmative evidence to prove a feasible alternative design through expert testimony. *See Gleason v. Crown Equip. Corp.*, 19-CV-11126, 2023 WL 2696198, at *4 (E.D. Mich. Mar. 29, 2023).

"Ultimately, Michigan law employs a 'stringent standard' when evaluating a claim of negligent design." *Kraft v. Dr. Leonard's Healthcare Corp.*, 646 F. Supp. 2d 882 (E.D. Mich. 2009) (quoting *Fisher v. Kawasaki Heavy Ind., Ltd.*, 854 F. Supp. 467, 471 (E.D. Mich. 1994)).

Here, Plaintiff has proffered through her expert Dr. Rosenzweig three alternative designs for the TVT-O: (1) "Ultrapro in either a pubovaginal sling or retropubic sling," (2) "a retropubic sling using human tissue in a cadaveric form," or (3) "a retropubic sling like the TVT." Trial Tr. 825:4–7. Her evidence supporting each of these proposed alternatives is insufficient under Michigan law.

Defendants recognize that this Court denied judgment as a matter of law at the close of Plaintiff's case on this point, but Defendants urge the Court to evaluate not just whether Dr. Rosenzweig has mentioned alternative designs, but whether Plaintiff's evidence regarding alternative designs satisfies the elements required under Michigan law.

A. Plaintiff lacks sufficient evidence that Ultrapro mesh is a safer alternative design.

Plaintiff's first proposed alternative design is Ultrapro mesh, used in either a pubovaginal sling or retropubic sling. Trial Tr. 825:4–7. Plaintiff's evidence on this proposed alternative is inadequate as a matter of law.

Not a product design. First, "Ultrapro in either a pubovaginal sling or retropubic sling," is not even a product design at all. *See* Mich. Comp. Law

600.2946(2). Dr. Rosenzweig did not testify that the TVT-O should have been made with Ultrapro. Rather, his testimony is that some unspecified "pubovaginal sling or retropubic sling" made of Ultrapro would be safer. But "pubovaginal" or "retropubic" are not product designs—they are simply surgical approaches. Dr. Rosenzweig does not actually describe any design for an actual product to be used. Mich. Comp. Law 600.2946(2). Plaintiff therefore cannot use this notion to satisfy her alternative design burden.

Not available. In addition, Ultrapro is not "developed, available, and capable of use" for the treatment of stress urinary incontinence. Mich. Comp. Law 600.2946(2). Ultrapro is a partially absorbable mesh material which is used in the hernia application. It is undisputed that Ultrapro is not available for sale in the United States because it has not been cleared or approved by the FDA for the treatment of stress urinary incontinence. Trial Tr. 937:15–17 (testimony from Dr. Rosenzweig that he is not aware of any sling made of Ultrapro that was cleared by the FDA in 2011, or even today); *see also id.* 937:21–25. Nor has Plaintiff put forth any evidence whatsoever to show that the design would, with any probability, have been cleared by the FDA. *See Robinson v. Ethicon*, No. H-20-3760, 2021 WL 5054648 at *7 (S.D. Tex. Nov. 1, 2021) (rejecting larger-pore mesh as a safer alternative because plaintiff did not establish it was "capable of being developed": "Robinson did not designate a regulatory expert who could testify about the FDA's

approval process or how such an application would have been viewed"). In fact, Ethicon did have a project called Project TOPA to develop TVTO-PA, a TVT-O made with partially absorbable mesh, but the FDA did not clear the device. Trial Tr. 562:14–565:18; DX20058. Ethicon could not get the project past cadaver labs because of issues with the partially absorbable mesh sticking to the sheath, and the project was canceled. Trial Tr. 559:9–562:1; *see also* Smith Tr. 649:9–15, ECF No. 235-8, p. 12. Plaintiff has not offered any evidence to suggest that a stress urinary incontinence mesh made of Ultrapro would have received FDA clearance, nor that it was or could have been available at the time of Plaintiff's TVT-O implantation in 2011.

Would not prevent the harm. Plaintiff has offered no evidence that the Ultrapro would prevent the harm here. Mich. Comp. Law 600.2946(2).[2] Plaintiff's expert did not say that the Ultrapro would *prevent* the harm, only that it would "substantially reduce *or* eliminate" the harm. *See* Trial Tr. 848:10–20

[2] Plaintiff contends that she need only show the harm would be "substantially reduced," but the statute is unequivocal that the harm must be "prevented" by the alternative design. Mich. Comp. Laws § 600.2946(2) (emphasis added); *see also Hershey v. Black & Decker (U.S.), Inc.*, 2008 WL 4414242, at *2 (Mich. Ct. App. Sept. 30, 2008) ("Contrary to plaintiff's argument on appeal, it is not sufficient that a plaintiff merely show that an alternative design would have reduced the risk of harm."). The Court has agreed that the standard is "prevent." Trial Tr. 1061:5–16. But even if the standard were "substantially reduced the harm," Dr. Rosenzweig's conclusory opinion entirely lacks data or supporting scientific evidence and is insufficient to meet Plaintiff's burden.

("substantially reduce[] . . . or eliminate[]"), *id.* 849:1–14 (same). Indeed, Dr. Rosenzweig agrees that ***all*** stress urinary incontinence surgeries—which would include any Ultrapro procedure—carry the risks of injury to structures like organs and nerves; pain, including persistent pain; dyspareunia, including persistent dyspareunia; and voiding dysfunction. Trial Tr. 994:3–21. Plaintiff's treating physician Dr. Michael Hibner also testified that "every surgery in the vagina can cause pudendal neuralgia," *id.* 376:8–13, and that "any pelvic surgery can cause pelvic floor spasms," *id.* 383:16–22.

No evidence that an Ultrapro mesh device would be safer and effective at treating Ms. Dandy's incontinence. Similarly, Plaintiff has no evidence of the safety and effectiveness of an Ultrapro mesh device. Although Dr. Rosenzweig testified in conclusory fashion that Ultrapro would be safer and as effective at TVT-O, he offers no support or explanation for that statement. Trial Tr., 824:24–825:23, 854:12–17. As with the allograft, Plaintiff has offered no data supporting the Ultrapro. There is no stress urinary incontinence device made with Ultrapro sold in the United States. Where a plaintiff "proffers an alternative design that is not currently in use," she bears a "'heavy burden' [to show that] the chosen design was unreasonably dangerous." *Fisher v. Kawasaki Heavy Indus. Ltd.*, 854 F. Supp. 467, 470–71 (E.D. Mich. 1994) (quoting *Owens v. Allis-Chalmers Corp.,* 414 Mich. 413, 430 (1982)). "To satisfy the 'heavy burden' created by *Owens* under such

circumstances," the plaintiff must show "that the chosen design was unreasonably dangerous" using "compelling empirical evidence of an alternative design." *Id*. at 471. "Such empirical evidence will probably most often take the form of testing, but must objectively show acceptability, utility, feasibility (including cost), and general safety of the proposed alternative design vis-à-vis the allegedly defective design." *Id.* An expert "who has never made or seen the alternative design he proposes, and therefore has no idea of its feasibility, utility, or cost" cannot establish alternative design. *Peck v. Bridgeport Machines, Inc.*, 237 F.3d 614, 618 (6th Cir. 2001).

As noted above, Dr. Rosenzweig does not even specify an actual product design using Ultrapro, much less test it or provide other empirical evidence supporting its safety and efficacy vis-à-vis the TVT-O. *Cf.* Smith Tr. 638:15–639:9, ECF No. 235-8, pp. 11–12 (describing that the elongation properties of Ultrapro made it unsuitable for an SUI product). Plaintiff's references to internal documents discussing the Ultrapro do not suffice. *Cowen v. Am. Med. Sys., Inc.*, 05-10307-BC, 2006 WL 3542704, at *2 (E.D. Mich. Dec. 7, 2006) ("Plaintiff has not shown the viability of an alternate design because Defendant's internal documents, Plaintiff's only record support, reveal only a design option, not the design's usefulness or superiority over other designs.").

Further, Dr. Rosenzweig does not address at all the additional risks that the Ultrapro would pose in order to compare them to the risks of the TVT-O. This too is a required element under Michigan law. Mich. Comp. Law 600.2946(2). For example, the expert must explain why the alternative "would not have led to more accidents than it prevented." *Taillard v. Rooto Corp.*, 787 F. App'x 281, 284 (6th Cir. 2019). As the Sixth Circuit held in *Peck v. Bridgeport Machines*, applying Michigan law, even where the expert testified that the alternative design would prevent the harm that the Plaintiff suffered, that is insufficient to establish a claim where the expert "offered no experiential basis for that opinion and did not testify as to whether the design would have been safer overall." *Peck*, 237 F.3d at 618; *Fisher v. Kawasaki Heavy Industries, Ltd.*, 854 F. Supp. 467, 471 (E.D. Mich. 1994) ("[I]n a case where the magnitude of the risks is uncertain—and the proposed alternative design is not in use—the mere assertion by an expert that a proposed alternative would have been 'safer' is insufficient to create a question of fact as to whether or not the chosen design was 'defective.'"). As explained above, Dr. Rosenzweig acknowledged that these risks exist with all stress urinary incontinence surgeries, but he does not address them. Dr. Rosenzweig cites no studies regarding the effectiveness or the safety of using Ultrapro for stress urinary incontinence; meanwhile, Defendants' expert Dr. Peter Rosenblatt testified that a larger-pore mesh

like Ultrapro "hasn't been tested" and therefore there is no way to know (much less testify) whether "a bigger pore [mesh] . . . would work." 5/1/23 Trial Tr.

No evidence of economic feasibility. Plaintiff has offered no evidence whatsoever of the economic feasibility of the Ultrapro. Mich. Comp. Law § 600.2946(2). Dr. Rosenzweig made a conclusory statement that all the alternatives he offered are "feasible," but he did *not* establish that they were *economically* feasible, Trial Tr. 825:4-5, because he never conducted that analysis. Under Michigan law, "[a]n expert's mere reference to, or description of, alternative designs, without addressing how practicable the manufacture of these designs would be or the estimated costs of production of these alternative designs, 'is not sufficient, as a matter of law, to invite the trier of fact to consider the alternatives.'" *Berry v. Crown Equip. Corp.*, 108 F. Supp. 2d 743, 756 (E.D. Mich. 2000). Plaintiff's lack of evidence on this element is fatal to her claim that Ultrapro is a safer alternative design.

B. Plaintiff's evidence regarding allograft slings as a safer alternative design is insufficient.

Plaintiff's second proposed alternative is an "allograft" retropubic sling. Trial Tr. 825:4–7. An "allograft" is tissue from another human which undergoes processing and is sold in a sheet. Plaintiff's evidence regarding the allograft as a safer alternative design is insufficient for multiple reasons:

Not an alternative design. As with the Ultrapro, Dr. Rosenzweig does not even identify an alternative product design at all—only a general type of material and a surgical approach. There are companies that sell allograft material, but Dr. Rosenzweig did not even propose a particular allograft product. This is not a "design" for any product under Mich. Comp. Law 600.2946(2).

An allograft is not a medical device, but rather is regulated by the FDA as human tissue for transplantation. *See* 21 C.F.R. Part 1271. An allograft sling is therefore not a safer alternative design for the TVT-O at all—it is a completely different product. As one district court has explained applying Michigan law, an alternative product that uses "bovine, porcine, or human cadaver dermis" is not an alternative design for a mesh product and cannot support a design defect claim. *See, e.g.*, *Barnes v. Medtronic, PLC*, No. 2:17-cv-14194, 2019 WL 1353880, at *2 (E.D. Mich. March 26, 2019). Numerous other courts have reached the same conclusion.[3]

[3] *See, e.g.*, *Burris v. Ethicon*, No. 3:20-cv-01450-JRK, 2021 WL 3190747, at *8 (N.D. Ohio July 28, 2021) (explaining allografts are not alternative designs because "at base, they are not different designs for the medical product polypropylene mesh products . . . but rather completely different procedures subject to completely different regulations"); *Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 908 (S.D. Iowa June 3, 2020) (rejecting allografts as "comparable products" or "comparable design concepts" because allografts are "regulated by the FDA as human tissues for transplantation"); *Robinson v. Ethicon*, No. H-20-3760, 2021 WL 5054648 at *5 (S.D. Tex. Nov. 1, 2021) (concluding the allograft sling, autologous facial sling, and paravaginal repair were not safer alternative designs for the TVT-O sling because they are "entirely different procedures or products"); *Labiche v. Johnson & Johnson*, 2021 WL 3719554, at *2 (S.D. Tex. Aug. 19, 2021) ("The use of organic sling

Would not prevent the harm. Plaintiff has offered no evidence that the allograft would prevent the harm here. Mich. Comp. Law § 600.2946(2). As with the Ultrapro, Dr. Rosenzweig did not testify that this product would prevent the harm, only that it would "substantially reduce[] . . . *or* eliminate[]" the harm. Trial Tr. 851:6–9 (emphasis added).[4]

No evidence that an allograft sling would be effective at treating Ms. Dandy's incontinence. Plaintiff has offered no evidence that the allograft would not "significantly impair[] the usefulness" of the device at treating SUI. Mich. Comp. Law § 600.2946(2); *see also TIG Ins. Co. v. Carrier Corp.*, No. 216793, 2000 WL 33419407, at *2 (Mich. Ct. App. May 23, 2000) (holding plaintiff must "demonstrate the efficacy of his proposed alternative designs" as part of his "prima facie case for a defective product"); *Taillard v. Rooto Corp.*, 787 F. App'x 281, 284 (6th Cir. 2019) ("[E]ven assuming that Magee's deposition testimony creates a genuine issue of material fact about whether the breakable seal would have prevented Taillard's accident, Taillard has failed to create a genuine issue of material fact about whether the alternative seal would not have 'creat[ed] equal or greater risk of harm' or

material is not a change in the design of the TVT-S pelvic mesh but a different product. The TVT-S pelvic mesh is intended as a synthetic product. Alternative types of mesh are not an alternative *design.*").

[4] Even if the standard were "substantially reduce" the harm, Plaintiff did not provide any empirical evidence supporting this opinion, just Dr. Rosenzweig's say-so.

'significantly impair[ed] the usefulness or desirability of' Rooto's product. And a products-liability plaintiff in Michigan must establish both of those elements.") (citations omitted). To the contrary, Dr. Rosenzweig admitted that "the allograft slings *might be a little bit less effective than the TVT-O*" in treating SUI. Trial Tr. 854:12–17 (emphasis added). And Defendants' expert Dr. Rosenblatt testified that studies show that TVT-O has a better success rate than allograft slings. 5/1/23 Trial Tr.

No evidence that an allograft sling would be safer without creating equal or greater risk of harm. Plaintiff also does not address the additional risks an allograft would impose. As explained above, Dr. Rosenzweig acknowledges the risks of all stress urinary incontinence surgeries. But he fails to assess those risks against the TVT-O's to explain why an allograft "would have been safer overall." *Peck*, 237 F.3d at 618; *Fisher v. Kawasaki Heavy Industries, Ltd.*, 854 F. Supp. 467, 471 (E.D. Mich. 1994) ("[I]n a case where the magnitude of the risks is uncertain—and the proposed alternative design is not in use—the mere assertion by an expert that a proposed alternative would have been 'safer' is insufficient to create a question of fact as to whether or not the chosen design was 'defective.'"). Plaintiff has repeatedly stressed the need for long-term data, and yet she offered no long-term data supporting the allograft. While Plaintiff put on no evidence that an allograft would not introduce equal or greater risk of harm, Defendants' expert Dr. Rosenblatt

testified that SUI procedures using a woman's own tissue have a complication rate "more than twice that" of TVT-O, a "10 or maybe even 15 percent complication rate." 5/1/23 Trial Tr.

No evidence of economic feasibility. Finally, as with the Ultrapro, Plaintiff has offered no evidence whatsoever of the economic feasibility of the allograft. Mich. Comp. Law 600.2946(2). Without evidence of the economic feasibility of their proposed alternative, Plaintiff's design defect claim fails.

C. Plaintiff does not establish that a TVT retropubic sling is a safer alternative design for the TVT-O.

Plaintiff's third proposed alternative is a TVT, which is a device sold by Ethicon that has the same mesh as the TVT-O but is implanted through a retropubic approach. Trial Tr. 825:4–7. Despite his insistence that the TVT is defective and unreasonably dangerous, Dr. Rosenzweig claims it is a safer alternative design. It cannot be as a matter of law.

Not a design for the TVT-O. The TVT is not an alternative design for the TVT-O, it is a different kind of surgery available to physicians. A different kind of surgery not chosen by the implanting physician cannot be an alternative design because the physician makes his choice based on his own skill and experience with that particular technique and the specific factors the physician is treating. This is a general principle in product liability law. *See, e.g.*, *Linegar v. Armour of America Inc.*, 909 F.2d 1150, 1154 (8th Cir. 1990) (contour bullet-proof vest with partially

exposed sides was not defectively designed, because "the amount of coverage was the buyer's choice," and "it is not the place of courts or juries to set specifications as to the parts of the body a bullet-resistant garment must cover"); *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) ("The problem with this argument is that it really takes issue with the choice of treatment made by [plaintiff's] physician, not with a specific fault of the pedicle screw sold by [defendant]"); *Talley v. Danek Med. Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (testimony about alternative surgery "did not indicate any design flaw in the Dyna-Lok Device. Rather, it questioned the medical judgment of doctors who use spinal fixation devices in surgery.").[5]

For this reason, another district court recently granted Ethicon's motion for summary judgment and held that retropubic slings involve a different procedure from the TVT-O and cannot serve as a feasible alternative design. *See Baksic v. Ethicon Inc.*, -- F. Supp. 3d. --, No. SA-20-CA-920, 2023 WL 2397498, at *9 (W.D. Tex. Mar. 6, 2023) (holding that "the use of retropubic slings involves a different

[5] *See also, e.g.*, *Hornbeck v. Danek Med., Inc.*, 226 F.3d 641 (5th Cir. 2000) (per curiam) (affirming summary judgment where alternative methods of treatment were identified by plaintiff, not alternative designs for the products at issue); *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014) ("A plaintiff cannot satisfy his burden to propose a feasible alternative design by proposing that an entirely different product could have been used"); *King v. Danek Med., Inc.*, 37 S.W.3d 429, 449 (Tenn. App. 2000) ("[Plaintiff's expert] did not propose an alternative design. . . . Instead, he recognized the existence of alternative . . . devices which do not utilize pedicle screws. . . . [S]uch dissimilar devices described by [the expert] have been determined not to be alternative designs").

procedure from the surgery used to implant the TVT-O device"). The same result is proper here.

Not reasonably safe. Plaintiff is asking the jury to determine that the TVT qualifies as a safer alternative design under Michigan law despite that her own expert testified that the TVT is both defective and unreasonably dangerous. Trial Tr. 935:16–936:8. Plaintiff is also asking the jury to determine that the TVT is a safer alternative design despite that Dr. Rosenzweig testified that pudendal neuralgia is a risk of the TVT and that the TVT would not have prevented or substantially reduced the risk of pelvic pain or dyspareunia. *Id.* 936:22–23, 937:3–9.

If the Court allows what Plaintiff's own expert considers to be a defective and unreasonably dangerous product to be a safer alternative design, it will be contrary to Michigan law. Plaintiff is required to "objectively show" the "general safety of the proposed alternative design." *Fisher*, 854. F. Supp. at 471; *see also* Mich. Comp. Laws § 600.2946(2) (requiring a safer alternative design that does not "create equal or greater risk of harm to others"). If the proposed alternative is also defective, then there is no way to avoid liability, which is not the law in Michigan. *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 181 (Mich. 1984) ("theories of products liability have been viewed as tort doctrines which should not be confused with the imposition of absolute liability.").

Judge Wolfson has already observed that "Dr. Rosenzweig fails to explain in detail his description of a retropubic sling as 'defective.'" ECF No. 95, at 31. At trial, not only has Dr. Rosenzweig not explained his characterization, he testified that the TVT is defective, unreasonably dangerous, carries a risk of pudendal neuralgia, and would not have prevented or substantially reduce Plaintiff's pelvic pain or pain with intercourse. If Dr. Rosenzweig's opinion that a defective and unreasonably dangerous device is a safer alternative design is allowed, then the Michigan statute and the case law interpreting it mean nothing.

Against Dr. Rosenzweig's lack of explanation of his testimony, Dr. Rosenblatt gave concrete examples of the different risks that TVT presents: bladder perforation and bowel perforation. 5/1/23 Trial Tr.

No evidence of economic feasibility compared to TVT. Plaintiff put on no evidence of the cost of producing TVT versus TVT-O. Instead, the only evidence on that issue in this case is that studies suggest "that transobturator may be more cost-effective compared with retropubic." 5/1/23 Trial Tr.

II. Plaintiff's claims based on a change in the mesh material are preempted by federal law.[6]

Under federal law, FDA clearance is required to market a device with a "significant change" in design or use. 21 U.S.C. § 360c(i)(1)(B); *see* 21 C.F.R. §

[6] Defendants recognize that the Court previously denied judgment as a matter of law on this basis at the close of Plaintiff's case, but Defendants re-raise it to preserve it.

807.100(a)(5). Clearance must be obtained if the device is "significantly changed or modified in design, components, methods of manufacture, or intended use." 21 C.F.R. § 807.81(a)(3). This includes "[a] change or modification in the device that could significantly affect the safety or effectiveness of the device, *e.g.*, a significant change or modification in design [or] material." "Conflict preemption" precludes the application of state law when it is "impossible for a private party to comply with both state and federal requirements or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 899 (2000) (internal quotations and citations omitted); *accord PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011) (citing *Wyeth v. Levine*, 555 U.S. 555, 583 (2009)). The rule that has emerged from Supreme Court holdings is, as stated in *Mensing*, "whether the private party could *independently* do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579 (emphasis added). And "independently," the Court explained, means *unilaterally*. *Id.* at 2580–81. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 293–300 (6th Cir. 2015) (under trio of Supreme Court cases, a medical product's design cannot be a legally cognizable safer alternative if marketing it would have required FDA's authorization).[7]

[7] Cases that interpret the above decisions make clear that the rules announced therein are not limited to a particular pharmaceutical context or to the particular facts at issue

Here, Ethicon could not have marketed a TVT-O with a different mesh material or other significant change in design without first obtaining clearance. Accordingly, any claim premised on such a theory is preempted.[8]

III. Plaintiff has not established evidence that entitles her relief from Michigan's cap on noneconomic damages.

As explained in Defendants' Letter Brief regarding Defendants' objections to Plaintiff's late-disclosed jury instructions and questions (ECF No. 233), Michigan caps noneconomic damages by statute. *See* Mich. Comp. Laws § 600.2946a. Defendants move for judgment as a matter of law on the only exception that remains after the Court's ruling on Defendants' motion for judgment as a matter of law at the close of Plaintiff's case: the exception to Michigan's lower cap, which requires that a defect in the TVT-O caused Plaintiff "death or permanent loss of bodily function."

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in those cases. *See, e.g.*, *Wos v. E.M.A.*, 133 S. Ct. 1391, 1398 (2013) (applying *Mensing* preemption to state law that purported to impose lien on Medicaid beneficiaries' tort recoveries); *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 703–04 (3d Cir. 2016) (discussing possible conflict preemption applied to Federal Aviation Administration regulations); *BP Am. Inc. v. Chustz*, 33 F. Supp. 3d 676, 699–700 (M.D. La. 2014) (applying impossibility preemption to state law cease-and-desist order that required removal of orphaned anchors and vessel ramp when it was impossible for BP to comply both with that order and with a federal on-scene coordinator's prohibition of the same); *Horseman's Benevolent & Protective Ass'n-Ohio Div. Inc. v. DeWine*, 666 F.3d 997, 997 (6th Cir. 2012) (Sutton, J.) (finding state law conflicts with a federal statute that requires consent of a horseman's group to off-track wagering).

[8] Nor could Plaintiff claim that state law can require a manufacturer to stop selling the device, an argument which has been rejected by the Supreme Court in *Bartlett*. *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2477-78 (2013).

Although Mich. Comp. Laws § 600.2946a does not define "permanent loss of a vital bodily function," the Michigan Court of Appeals defined the phrase "los[s] of a vital bodily function" in a separate damages-cap statute. *See Lewis v. Krogol*, 582 N.W.2d 524, 527 (Mich. Ct. App. 1998). It held that the phrase entails the loss of "bodily functions that are considered to have a high degree of importance." *Id.* at 527. In that case, the appeals court held that a plaintiff "in a wheelchair basically the whole day, other than to transfer to the couch" was entitled to have the jury answer whether she had lost a vital bodily function. *Id.* ("By including the word 'vital,' the Legislature indicated that not all injured patients who had lost a bodily function would be exempt from the cap.").

Plaintiff has no such evidence here. Here, Plaintiff's testimony was that sitting is "uncomfortable," she does not "have a woman's normal sexual life," and she has fecal incontinence. Trial Tr. 1075:5–6, 1088:7–9. Although Ms. Dandy said she "can't walk for any certain amount of time," she did not testify that she uses a cane, walker, or any other assistance to walk. Trial Tr. 1088:7–9.

To hold that pain during sexual intercourse or discomfort while sitting is sufficient to constitute "permanent loss of a vital bodily function" would be an unsupported extension of Michigan law. Plaintiff cited two cases in her letter brief to support her proposed jury question to suggest that the jury should decide this issue in this case. ECF No. 234. Like *Lewis*, both cases address whether the loss of the

ability to walk met the standard and in both cases there was evidence the plaintiff required assistance to walk. *See Peak v. Kubota Tractor Corp.*, 924 F. Supp. 2d 822, 834 (E.D. Mich. 2013); *Makki v. OSI Sealants*, Nos. 06-14328, 06-14329, 2008 WL 4378158, at *2 (E.D. Mich. Sept. 23, 2008). And in *Peak*, the Court recognized the distinction between a "permanent loss of a vital bodily function" and a "serious impairment": "the former requires something more than the latter." *Peak*, 924 F. Supp. at 834. Defendants are unable to locate a single case under Michigan law where pain with sitting or pain with sexual intercourse constituted a "permanent loss of a vital bodily function" under the statute. Plaintiff's injuries do not constitute a permanent loss of a vital bodily function as a matter of law.

Nor is there expert testimony in this case of a "permanent loss of a vital bodily function." Dr. Rosenzweig simply testified that Plaintiff's injuries are "significantly significant," that Plaintiff "can't have sexual intercourse" without pain, and that Plaintiff has "pelvic pain" "painful sitting." Trial Tr. 855:3–6.[9] And he never linked Plaintiff's alleged fecal incontinence to the TVT-O. Nor did Dr. Rosenzweig link a defect in the TVT-O to the alleged injury on which this Court denied Defendants'

[9] In a Letter Brief, Plaintiff accused Defendants of endorsing the "preposterous view" that painful sex is not a loss of bodily function because "sexual functioning" is essential to "the continuity of the human race." ECF No. 234, at 2. Plaintiff underwent a hysterectomy on the same day she underwent her implantation with the TVT-O.

motion for judgment as a matter of law at the close of Plaintiff's case—a reduced capacity to walk. Plaintiff has not established the permanent *loss* of a *vital* bodily function.

In response to Defendants' motion for judgment as a matter of law at the close of Plaintiff's case, Plaintiff did not respond at all on this issue. *See* ECF No. 238. Judgment as a matter of law is proper.

CONCLUSION

For these reasons, Plaintiff is unable to establish a claim for negligent design defect under Michigan law. Plaintiff is not entitled to any exception from the Michigan noneconomic damages cap. Ethicon respectfully requests that the Court enter judgment as a matter of law in its favor.

Respectfully submitted,

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